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Promoting prevention through meaningful measures: Improving the Centers for Disease Control and Prevention's National Healthcare Safety Network Urinary Tract Infection Surveillance Definitions

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The new year of 2015 brought with it the release of the update to the Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN) urinary tract infection (UTI) definitions. Although the NHSN UTI definitions were last updated in 2009, the inclusion of catheter-associated UTIs (CAUTIs) in the Centers for Medicare & Medicaid Services' Inpatient Quality Reporting Program in 2012 heightened the challenges to the definitions by many professionals involved in infection prevention. Feedback to CDC beginning in 2012 highlighted the gap between clinical and surveillance determinations of CAUTI[1], raised questions about the clinical relevance of some CAUTIs reported to NHSN and drew attention to variability in the application of, and adherence to, the UTI surveillance criteria and differences in clinical laboratory practices relevant to the criteria. Many commenters questioned the validity and fairness of using CAUTI data for public reporting and payment purposes and called for definitions which would more accurately measure the success of CAUTI prevention activities.

For these reasons, in early 2013, CDC began a systematic process of reviewing the NHSN UTI definitions. The main objectives of this work were to: 1) improve the objectivity, credibility, and reliability of the UTI definitions, 2) promote best practices for patient safety with a metric that is reflective of the success or failure of quality improvement and prevention activities, 3) develop a metric that is amenable to full electronic capture to allow for increased objectivity and reduced burden of data collection, and 4) help target CAUTI prevention.

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As part of the definition review process, CDC created an internal working group and identified a 14-member panel of external subject matter experts to assist in reviewing the issues related to the UTI surveillance definitions. The external experts included representatives from a variety of healthcare facility types, and public health agencies. Infection preventionists, microbiologists, infectious disease physicians, hospitalists, hospital epidemiologists, senior hospital and corporate administration, and other experts in CAUTI prevention all offered their insights and recommendations. CDC also worked with the Association of Professionals in Infection Control and Epidemiology (APIC) to conduct a survey of urine culturing and urinalysis practices in a convenience sample of laboratories. Data from NHSN were analyzed to address specific questions that arose during the discussions, and relevant literature was reviewed. Data and proposed definition modifications were presented to the Healthcare Infection Control Practices Advisory Committee (HICPAC) for discussion and feedback during two public meetings.[2] The major topics discussed included: 1) whether to include in the definitions, UTIs caused by yeasts; 2) whether urine cultures with low concentrations of organisms (i.e., < 100,000 colony forming units [CFU]/ml) should be a part of the UTI criteria; 3) whether urinalysis results should be a part of the UTI criteria; 4) options to improve the specificity of the UTI criteria, particularly in cases where fever is the only sign present; and, 5) whether modifications should be made to the UTI criteria for special populations (e.g., spinal cord injury patients).

The inclusion of yeasts such as *Candida* spp. as pathogens in the UTI definitions was one of the most frequently raised concerns by NHSN users. Yeasts are a common cause of CAUTIs reported to NHSN, particularly from intensive care units (ICUs); in 2013, yeasts accounted for 26.1% of CAUTIs reported (32.1% of CAUTIs from ICUs and 7.7% of CAUTIs from non-ICUs). However, in clinical practice, urine cultures positive for yeast, even >100,000 CFUs/ml, in hospitalized adult patients are typically considered urinary device colonization rather than infection,[3] and a randomized, controlled trial showed no clinical benefit of treatment with fluconazole among asymptomatic or minimally symptomatic patients.[4] Guidelines do not generally recommend therapy for treatment of asymptomatic candiduria. NHSN user feedback indicated that the lack of clinical relevance of yeast in urine cultures sometimes resulted in administrative overruling and underreporting by some facilities. In addition, the survey of clinical laboratories indicated variability in quantifying and reporting of yeasts in urine, resulting in facility differences in CAUTI reporting on the basis of existing laboratory practices.

Concern among the working group was raised about potential unintended consequences of removing yeasts from the definition, such as reducing incentives for facilities to remove urinary catheters. However, these theoretical concerns were weighed against the clinical concerns and the need for measures that can be applied fairly across most facilities and inform prevention efforts. Furthermore, reclassification of fungemia from secondary to primary bloodstream infections as a result of removing yeasts from the UTI definitions was considered favorable since yeast in the bladder rarely result in ascending urinary tract infection and seeding of the bloodstream.[5,6] In 2013, 1.0% of CAUTIs with yeast as the sole pathogen were reported to have secondary bloodstream infections. The reclassification of secondary fungemias as primary may better inform central line-associated bloodstream

infection (CLABSI) prevention efforts, acknowledging that the reverse misclassification may occur, particularly in immunocompromised patients. Tracking fungemia within the CLABSI data reported to NHSN will provide an on-going means of monitoring fungal infections with the most impact on patient safety. Therefore, to improve the clinical credibility of the UTI surveillance definitions and to reduce the variability in reporting, the CDC internal working group opted to remove yeasts from the UTI criteria. For the same reasons other rarely-reported non-bacterial pathogens (including non-yeast molds, virus and parasites) were also removed from the criteria. These pathogens represented < 0.2% of all reported CAUTIs between January 2009 and March 13, 2015.

The inclusion of urine cultures with low colony counts (<100,000 CFU/ml) in the UTI definitions was another issue considered by the working group and external experts. In the previous definition scheme, these cases were captured by the symptomatic UTI (SUTI) 2 definition[7] and required presence of a positive urinalysis in addition to at least one specified sign or symptom. Although a definitive CFU cut-off representing true UTI in catheterized patients has not been defined, such cut offs have been long recognized for bacteruria in non-catheterized women and lower concentrations of organisms in catheterized patients have been considered more likely to represent urinary colonization or contamination than infection.[8] Debate arose because some data point to the significance of urine cultures with lower colony counts, particularly one publication demonstrating that lower colony counts of growth in the urine quickly rise to > 100,000 CFU/ml and therefore may be clinically significant.[9] In addition, analysis of January 2009-May 2013 NHSN data demonstrated that the incidence of reported secondary bloodstream infection was similar for CAUTIs meeting the SUTI 1[7] (6.1%) and SUTI 2 (5.2%) criteria. However, potential problems in the reporting of CAUTIs with lower colony counts were identified. Analysis of 2013 NHSN data showed that < 10% of the CAUTIs reported to NHSN met the SUTI 2 definition and that only 43% of hospitals reporting CAUTIs used the SUTI 2 definition at all. Supporting the NHSN data, the clinical laboratory survey found that only 29% of the approximately 345 responding laboratories used a threshold as low as ≥ 1,000 CFU/ml (the SUTI 2 threshold) to trigger minimal identification of organisms in urine specimens collected from indwelling catheters, which is necessary for NHSN data entry. The apparent variability in the use of low colony count criteria for reporting suggests that the SUTI 2 data are not representative of what may actually be occurring in hospitals, and that facilities whose laboratories identify organisms from low colony counts may be penalized for reporting more CAUTIs than those whose laboratories don't. Therefore, the CDC internal working group decided to limit the threshold for the UTI surveillance definitions to ≥ 100,000 CFU/ml.

The working group also considered the use of the urinalysis as an element of the UTI definitions. In an effort to improve the specificity of the SUTI 2 criteria, the previous definitions required a positive urinalysis, defined as the presence of pyuria, leukocyte esterase, nitrite, or positive gram stain, when the urine culture colony count was < 100,000 CFU/ml. However, pyuria, particularly in the setting of a urinary catheter, is a non-specific finding and cannot be used to distinguish infection from colonization.[10] On the other hand, because the absence of pyuria suggests a diagnosis other than UTI,[10] consideration was given to the use of a negative urinalysis to allow for exclusion of reporting of bacteriuria as a UTI in immunocompetent patients. Review of the literature and discussions with

laboratory experts indicated that no standardized laboratory criteria for a positive or negative urinalysis have been defined, precluding the use of this measure for the surveillance definition. For this reason, the working group decided on the removal of urinalysis results as part of the NHSN UTI criteria.

Finally, the use of fever and other signs and symptoms used to meet the UTI definition were reviewed. The first issue focused on the requirement to report a CAUTI with fever as the sole symptom even if another possible source of fever is identified. For the purposes of objectivity and equity, NHSN rules serve to minimize the use of clinical judgment in the reporting of healthcare-associated infections. Between January 1, 2009 and January 31, 2013, the majority of CAUTIs reported to NHSN used fever as the sole clinical criterion to meet the definition (79.7%). This is likely related to the absence of UTI-specific signs or symptoms in many hospitalized patients, a lack of assessment and/or documentation of such signs or symptoms, and methodologies reportedly used by some hospital surveillance programs (surveillance only for fever rather than full chart review).

The working group and external experts considered other alternatives to the current NHSN protocols, such as excluding reporting of a CAUTI if another NHSN-defined source of fever is identified. However, this strategy would require the identification of a hierarchy of infections deemed more likely to cause fever than UTI, a process that would be fraught with subjectivity and would create additional burden on infection preventionists who would be required to consider and rule out multiple alternative types of infection. A future automated hierarchical algorithm may be possible when data are fully captured electronically, but for now the decision was made to continue the current rules. It is likely that the changes to the definitions (i.e., removal of yeast and lower colony counts) will improve the specificity of the UTI criteria and reduce the potential impact of fever due to other sources. The working group members were also in agreement that no additional signs or symptoms would add value to the UTI definitions because of lack of objectivity, specificity, and feasibility for surveillance, particularly for future electronic capture. Signs and symptoms in special populations such as spinal cord injury patients[11] were discussed in detail but were deemed too non-specific or difficult to capture for the purposes of surveillance.

Our UTI definition review was multidisciplinary and extensive, but several operational limitations affected the scope and process of the review. Limited available data led us to rely on the best available scientific evidence and expert consensus to reach decisions. An analysis of clinical correlation of the revised definitions was not performed and would be limited by the lack of a gold standard clinical definition of CAUTI. In addition, because there are no clinical biomarkers for UTI or standardized criteria for existing measures such as the urinalysis, we could not incorporate additional, objective laboratory criteria to improve the specificity of the definitions. With advances in diagnostic technology and further research to determine the association of objective laboratory criteria with clinical findings, we hope that more objective criteria can be used in the future, both for clinical and surveillance purposes. Finally, we attempted to better understand current clinical laboratory practices for UTI diagnosis with a survey of clinical laboratories conducted by APIC. While the survey was useful in the variability of practices it revealed, it cannot be considered

representative of all clinical laboratories as only approximately 340 out of > 14,000 invited facilities responded.

In summary, CDC has responded to user and stakeholder feedback by completing an extensive review and revision of the NHSN UTI definitions. The objective was to modify the definitions to create a meaningful comparative metric with maximal credibility, objectivity, equitability, and amenability to future transition to electronic surveillance, and to guide CAUTI prevention. Improving the credibility of the definition will hopefully narrow the gap between clinical and surveillance definitions and focus more attention on implementing CAUTI prevention practices and less on the definitions. The need to have surveillance definitions that use objective criteria that all facilities can meet in a similar manner to improve comparability of reported data highlights the gap between surveillance and clinical definitions; UTIs captured by surveillance serve as a proxy indicator and may not be inclusive of all clinical UTIs. Importantly, the definition review has highlighted the need for collaborations between public health and professional societies to develop clinical laboratory standards for urine culturing and urinalysis.

Given that CAUTIs identified by the revised criteria will be a subset of the previous CAUTIs captured, it will be possible for facilities to estimate previous CAUTI rates and SIRs to allow for trend analysis over time; however, several other general changes were made to the NHSN HAI definitions in 2015, the impacts of which are unknown. These include 1) the institution of a 7-day infection window period, 2) the institution of a 14-day repeat infection window period, and 3) changing the definition of the date of event from the date of the last element of the infection criteria to the date that the first infection element occurred during the infection window. These modifications to HAI surveillance definitions will each affect the reporting of CAUTIs by changing the time period during which all elements of infection must be present to meet criteria, how new infections are discriminated from previous infections, or how infections are determined to be present on admission vs. healthcare-associated. These changes will also improve objectivity and more easily enable transition to electronic surveillance. In 2016, CAUTI SIRs will be calculated using a new baseline of 2015 data, and CAUTI SIRs will continue to be monitored to determine improvement and success of CAUTI prevention activities. It is hoped that the revised metric will more accurately reflect the impact of such prevention activities.

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